

REMARKS

Claims 1, 14-16 and 18-27 are currently pending. After cancellation of claims 19 and entry of new claims 29-61, claims 1, 14-16, 18, 20-27, 29-61 will be pending.

The above amendments enter no new matter. Support for new claims 29-32 can be found throughout the application, for example at page 10, line 20 to page 11, line 16. Support for new claims 33 and 34 can be found, for example, at page 6, lines 6-11. Support for new claim 35 can be found, for example, at page 6, lines 12-14. Support for new claims 36, 37 and 38 can be found, for example, at page 6, lines 28-33. Support for new claim 39 can be found, for example, at page 6, line 30. Support for new claims 40 and 41 can be found, for example, at page 6, lines 18-22. Support for claims 42-47 can be found throughout the application, for example at page 10, line 20 to page 11, line 16, and in the claims as originally filed.

Support for new claims 48 and 49 can be found, for example, at page 6, lines 6-11. Support for new claim 50 can be found, for example, at page 6, lines 12-14. Support for new claims 51, 52 and 53 can be found, for example, at page 6, lines 28-33. Support for new claim 54 can be found, for example, at page 6, line 30. Support for new claims 55 and 56 can be found, for example, at page 6, lines 18-22. Support for new claims 57, 58 and 59 can be found, for example, in the claims as originally filed. Support for new claim 60 can be found at page 11, lines 30-33. Support for new claim 61 can be found, for example, at page 12, lines 12-16. Note that, where units of measure used in the claims are supported in the specification in U.S. units such as inches, and equivalent metric units have been included in parentheses. Applicants respectfully reserve the right to pursue any subject matter otherwise withdrawn from consideration with this action.

Rejection under 35 U.S.C. §102(b)

The Office Action states that claims 1, 14, 18 and 20 have been rejected under 35 U.S.C. §102(b) as being anticipated by Chuttani *et al.* (U.S. Patent No. 5,054,501). In particular, the Office Action specifically states that Chuttani *et al.* anticipates Applicants device claims 1, 14 and 18, because it teaches “a medical device comprising a generally longitudinally-extending wire core, a portion of the core forming a helical coil which

tapers in diameter from a larger diameter to a smaller diameter” (citing Chuttani *et al.* at col. 3, lines 20-24). Applicants respectfully traverse the rejection for the reasons that follow.

First, Applicants note that the cited section of Chuttani *et al.* teaches a preferred embodiment in which the wire shaft itself, not the coil into which it is formed, tapers near the distal end of the guide wire. Indeed, Chuttani *et al.* states “to facilitate increased flexibility at the distal end, the preferred embodiment of the wire shaft (10) decreases in diameter throughout a tapered portion (16) near the distal end (12) of the guide wire (5).” Furthermore, the cited portion of Chuttani *et al.* refers to FIG. 1 of that patent, which specifically depicts a constant-diameter helical coil (15). Accordingly, the cited section of Chuttani *et al.* does not teach a helical coil that tapers from a proximal larger diameter end to a distal smaller diameter end as claimed in the instant invention, but rather a tapering wire formed into a constant-diameter helical coil.

Second, Applicants note that a detailed inspection of all the teachings of Chuttani *et al.* reveal no disclosure or guidance toward a tapering shape for the helical coil. Indeed, FIG.3, FIG. 4 and FIG. 6 of the Chuttani *et al.* patent, all of which show the coiled portion of the device, always depict it as a constant-diameter helical coil. Furthermore, FIG. 2 depicts the tapered shape of the wire shaft itself, consistent with Applicant’s reading of the cited section of this reference. Therefore, Chuttani *et al.* simply fails to teach the “helical coil which tapers in diameter from a larger diameter end at the proximal end thereof to a smaller diameter end at the distal end thereof”, as required by device claims 1, 14, and 18. Furthermore, since medical procedure claim 20 requires the medical device according to claim 18, it also cannot be anticipated by the teachings of the Chuttani *et al.* patent either for the same reason. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

The Office Action further states that medical procedure claims 20-23 have been rejected under 35 U.S.C. §102(e) as being anticipated by Fina (U.S. Patent No. 6,248,113). In particular, the Office Action states that Fina teaches “a medical procedure comprising the steps of: providing a medical device according to claim 18 (fig.6) in a configuration in which the helical coil of the guide wire of the device is retracted into the

tubular sheath of the device...”. Applicants respectfully traverse this rejection for the reasons that follow.

First, as an initial matter, Applicants respectfully note that the Fina reference teaches an “electrolytic dissolution” device, and associated electrolytic dissolution method, for electrically dissolving urinary stones, while Applicants’ device, and associated medical procedure, is an “entraining” device for physically capturing and removing such stones. Indeed, Applicant’s note for the record that, while the Office Action states that Fina teaches a device for performing lithotripsy, “wherein the lithotripsy comprises one of electrohydraulic, pneumatic pulse, acoustic shock wave, and laser lithotripsy” (citing col. 1, lines 49-56), the cited section of Fina actually refers to Fina’s summary of the prior art, and not to methods to be used in conjunction with Fina’s device. Accordingly, the Fina reference teaches a fundamentally different device that employs a fundamentally different strategy for the removal of biological calculi.

Second, the Fina reference does not teach “a medical device according to claim 18,” and, accordingly, as a matter of claim construction, the reference cannot anticipate Applicants’ method claims 20-23, which require all the elements of claim 18. Indeed, the device taught by Fina is fundamentally different from that claimed by the Applicant. In particular, the superficial resemblance to Applicants’ invention of the embodiment shown in cited Figure 6 of Fina belies fundamental distinctions in the construction and design. For example, in the embodiment shown in Figure 6 of Fina, the conical-shaped element (10) is an “additional anode electrode” (see col. 4, lines 6-18) and not a mechanical entrainment device made out of “a super-elastic deformable material,” as required by Applicants’ claim. Indeed, to the extent that the device taught by Fina involves an elastic element at all, it employs, “advantageously,” a very different spring mechanism (18) at the proximal end of the device as shown in Fig. 9 of Fina (see col. 4, lines 23-28). Still further, Applicants note that Fina *et al.* provide this “additional anode electrode” “within an additional probe (11),” yet this additional probe (11) is not taught to be “a flexible tubular sheath surrounding” the “additional anode electrode” element as would be required by the second element of Applicants’ claim 18.

Accordingly, since the Fina reference fails to teach every element of the medical device of claim 18, it cannot anticipate Applicants’ associated method of use claims,

which depend from, and therefore require all elements of, the device of claim 18.
Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Rejection under 35 U.S.C. §103

The Office Action further states that claims 20-23 have been rejected under 35 U.S.C. §103 as being unpatentable over Chuttani *et al.* (U.S. Patent No. 5,054,501) in view of Samson *et al.* (U.S. Patent No. 6,066,149). Applicants respectfully traverse this rejection for the reasons cited above in rebutting Chuttani *et al.* as anticipatory prior art over claim 18, from which rejected claims 20-23 depend.

In particular, Applicants have explained above that the Chuttani *et al.* reference does not teach or suggest “a helical coil which tapers in diameter from a larger diameter to a smaller diameter,” as required by Applicants’ medical device claim 18, and, consequently, method claims 20-23, which depend from this claim.

Furthermore, Applicants note here that these deficiencies in the teachings of Chuttani *et al.* are not made up for by the teachings of the Samson *et al.* reference. Indeed, Samson *et al.* describes a very different type of device that is used to remove clots and is cited for teaching “a device with a common alloy comprising nickel and titanium or nickel, titanium, and chromium.” Nowhere does the Samson *et al.* reference teach or suggest a “a helical coil which tapers in diameter from a larger diameter to a smaller diameter.” Accordingly, Samson *et al.* does not correct this deficiency in the teaching of the Chuttani *et al.* reference.

Since all of the elements of a claim must be taught or suggested by one or more of the cited references, or must otherwise be established to be well recognized in the art at the time of the invention, to support a rejection for obviousness, Applicants respectfully assert that the cited art does not, and indeed cannot, render the claimed invention obvious under 35 U.S.C. §103. Therefore reconsideration and withdrawal of the rejection is respectfully requested.

Obviousness-Type Double Patenting

The Office Action still further states that claims 1 and 24 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 13 and 14 of U.S. Patent No. 6,620,172. While Applicants do not acquiesce to a holding that issued claims 1, 13 and 14 of U.S. Patent No. 6,620,172 render the instant claims 1 and 24 obvious, they respectfully request that this rejection be held in abeyance until a finding of patentable subject matter has been made. At that time, the question of whether issued claims 1, 13 and 14 of U.S. Patent No. 6,620,172 render any of the allowed claims obvious under the judicial doctrine of obviousness-type double patenting will be addressed in view of the scope of those allowed claims.

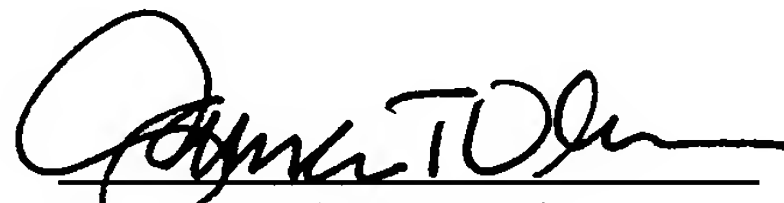
The Office Action also states that claims 15, 16, 20 and 27 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 13 and 14 of U.S. Patent No. 6,620,172 in view of Samson *et al.* (U.S. Patent No. 6,066,149). The Office Action further states that claims 18 and 19 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18 and 19 of U.S. Patent No. 6,620,172 in view of Chuttani *et al.* (U.S. Patent No. 5,054,501). As stated above for the first such obviousness-type double patenting rejection, Applicants respectfully request that this rejection be held in abeyance until a determination of allowable subject matter has been made. At that time the propriety of the rejection will be addressed in view of the scope of the allowed claims.

CONCLUSION

Applicant believe that the presently maintained rejections of the pending claims have been fully overcome by the amendment and arguments presented above. Accordingly, Applicant respectfully submits that the pending claims are in condition for allowance, and prompt acknowledgment of such is respectfully requested. If the Examiner believes that any further discussion of this communication would be helpful, he is encouraged to contact the undersigned by telephone.

The time for responding to this action has been extended to November 27, 2004 by the accompanying Petition for a One Month Extension of Time and payment of fee. No additional fees are believed to be due in connection with this communication, however, please apply any additional charges, or credit any overpayment, to our Deposit Account No. 08-0219.

Respectfully submitted,



James T. Olesen, Ph.D.
Registration No. 46,967
Attorney for Applicants

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000
(617) 526-5000 (fax)

Date: November 24, 2004